

PATENT COOPERATION TREATY

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From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

Amersham Biosciences AB
Patent Department
Björkgatan 30
751 84 Uppsala
Sverige

11 Feb 2006
RP ✓
UA
15/12/05
PU03103-PCT

PCT

WRITTEN OPINION OF THE
INTERNATIONAL PRELIMINARY
EXAMINING AUTHORITY

(PCT Rule 66)

Date of mailing
(day/month/year)

13 -12- 2005

Applicant's or agent's file reference

PU03103 - PCT

REPLY DUE

within 60 days from
the above date of mailing

International application No.

PCT/SE2004/001872

International filing date (day/month/year)

15.12.2004

Priority date (day/month/year)

23.12.2003

International Patent Classification (IPC) or both national classification and IPC

See Supplemental Box

Applicant

Amersham Biosciences AB et al

1. ☒ The written opinion established by the International Searching Authority:
☒ is ☐ is not
considered to be a written opinion of the International Preliminary Examining Authority.
2. This second (first, etc.) opinion contains indications relating to the following items:
 - ☒ Box No. I Basis of the opinion
 - ☐ Box No. II Priority
 - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - ☒ Box No. IV Lack of unity of invention
 - ☒ Box No. V Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - ☐ Box No. VI Certain documents cited
 - ☐ Box No. VII Certain defects in the international application
 - ☒ Box No. VIII Certain observations on the international application
3. The applicant is hereby invited to reply to this opinion.

When? See the time limit indicated above. The applicant may, before the expiration of that time limit, request this Authority to grant an extension, see Rule 66.2(e).

How? By submitting a written reply, accompanied, where appropriate, by amendments, according to Rule 66.3. For the form and the language of the amendments, see Rules 66.8 and 66.9.

Also For the examiner's obligation to consider amendments and/or arguments, see Rule 66.4bis. For an informal communication with the examiner, see Rule 66.6. For an additional opportunity to submit amendments, see Rule 66.4.

If no reply is filed, the international preliminary examination report will be established on the basis of this opinion.
4. The final date by which the international preliminary report on patentability (Chapter II of the PCT) must be established according to Rule 69.2 is: 23.04.2006

Name and mailing address of the IPEA/SE

Patent- och registreringsverket

Box 5055

S-102 42 STOCKHOLM

Facsimile No. 46 8 667 72 88

Form PCT/IPEA/408 (cover sheet) (April 2005)

Authorized officer

Jens Waltin/EÖ

Telephone No. 46 8 782 25 00

**WRITTEN OPINION OF THE
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY**

International application No.

PCT/SE2004/001872

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of: Cover sheet

INTERNATIONAL PATENT CLASSIFICATION (IPC) :

B01D 57/02 (2006.01)

G01N 27/26 (2006.01)

WRITTEN OPINION OF THE
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

International application No.

PCT/SE2004/001872

Box No. I Basis of the opinion

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into _____,
which is the language of a translation furnished for the purposes of:
- ☐ international search (Rules 12.3(a) and 23.1(b))
- ☐ publication of the international application (Rule 12.4(a))
- ☐ international preliminary examination (Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this opinion has been established on the basis of (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed."*):

- ☐ the international application as originally filed/furnished
- ☒ the description:
pages 1 - 7 _____ as originally filed/furnished
pages _____ received by this Authority on _____
pages _____ received by this Authority on _____
- ☒ the claims:
pages _____ as originally filed/furnished
pages _____ as amended (together with any statement) under Article 19
pages 8 - 9 received by this Authority on 19-10-2005
pages _____ received by this Authority on _____
- ☐ the drawings:
pages _____ as originally filed/furnished
pages _____ received by this Authority on _____
pages _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This opinion has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

WRITTEN OPINION OF THE
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

International application No.

PCT/SE2004/001872

Box No. IV Lack of unity of invention

1. ☐ In response to the invitation (Form PCT/IPEA/405) to restrict or pay additional fees the applicant has, within the applicable time limit:
- ☐ restricted the claims
 - ☐ paid additional fees
 - ☐ paid additional fees under protest and, where applicable, the protest fee
 - ☐ paid additional fees under protest but the applicable protest fee was not paid
 - ☐ neither restricted the claims nor paid additional fees

2. ☒ This Authority found that the requirement of unity of invention is not complied with for the following reasons and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees:

The following separate inventions have been identified:

1) Claims 1 and 13 (and 2-8, 11-12 and 14-16), relating to the use of a hydrophilic support derivatised with positively charged groups, for sample application to an IPG gel.

2) Claim 18 (and 9-10, 17 and 19) relating to a sample applicator for IPG electrophoresis, comprising regenerated cellulose derivatised with cation groups.

The most relevant prior art is represented by WO 96/27787 A1 (D1).

For reasons set out in box 5, claims 1 and 13 lack an inventive step with respect to D1.

Consequently, claims 1 and 13 (invention 1) lack special technical features (STF) within the meaning of PCT Rule 13.2.

The distinguishing special technical features (STF) of claim 18 (invention 2) in relation to D1 is that the positively charged support is made of regenerated cellulose. In D1, the support is made of nylon.

Since claims 1 and 13 lack STF they have no STF in common with claim 18. The application hence does not meet the requirement of unity of invention as set out in PCT Rule 13.1 and 13.2.

This could be amended by incorporating claim 2 (acidic interval pH gel) into claims 1, 13 and 18.

3. Consequently, this opinion has been established in respect of the following parts of the international application:

☒ all parts

☐ the parts relating to claims Nos. _____

WRITTEN OPINION OF THE
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Box No. V Reasoned statement under Rule 66.2(a)(II) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	_____
	Claims	_____
Inventive step (IS)	Claims	<u>1. 3-8. 11-14</u>
	Claims	_____
Industrial applicability (IA)	Claims	_____
	Claims	_____

2. Citations and explanations:

This opinion is based upon the amended claims filed with the letter of 19-10-2005.

Most relevant document cited in the International Search Report:

D1: WO 96/27787 A1

The invention relates to sample application to IPG gels, and more specifically to the problems faced when applying sample to acidic pH interval gels. The solution is to use a positively charged sample application support placed at the cathode side of the gel.

D1 discloses the use of a positively charged support for applying sample to the cathode side of an electrophoretic gel (refer to page 5, line 1-18, page 11, line 24 - page 12, line 9, figure 5b and claims 7 and 14).

The distinguishing feature of claims 1 and 13 in relation to D1 is that the sample is applied to an IPG gel. D1 relates to electrophoresis in general and does not specifically concern IPG gels.

According to your letter of 19-10-2005, the technical effect obtained when using the sample applicator with an IPG gel is that protein precipitation can be avoided.

The problem with protein precipitation is, however, associated with acidic pH interval gels. The effect is thus only obtained when using acidic pH interval gels. Yet, the invention as defined in claims 1 and 13 is not restricted to acidic pH interval gels.

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WRITTEN OPINION OF THE
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International application No.

PCT/SE2004/001872

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: BOX V

Therefore, the effect of avoiding protein precipitation is not necessarily obtained by the invention as claimed.

Consequently, since there is no particular effect, the problem solved by the invention in relation to D1 is just to decide in what kind of electrophoresis process D1 is to be applied.

It is not considered inventive to apply D1 to a previously known electrophoresis process, as long as it does not result in any particular or unexpected effect. Therefore, it is considered obvious to a person skilled in the art to apply the sample applicator disclosed in D1 to an IPG gel in isoelectric focussing, and thereby arrive at the invention as defined in claims 1 and 13.

Therefore, the invention according to claims 1 and 13 is considered to lack an inventive step.

Furthermore, the subject matter of dependent claims 3-8, 11-12 and 14 does not appear to differ essentially from what is known from D1. If it can be shown that some aspect covered by these claims provides unexpected effects and the claims are restricted accordingly, the judgement may be reconsidered. Until these conditions are met, claims 3-8, 11-12 and 14 are not considered to involve an inventive step.

It may be added that a skilled person who applies the sample applicator disclosed in D1 to an IPG gel would not arrive at the invention according to claims 9-10 or 17-19, according to which the sample applicator is made of regenerated cellulose. However, see box IV for comments regarding these claims.

**WRITTEN OPINION OF THE
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY**

International application No.

PCT/SE2004/001872

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

For clarity, the meanings of the abbreviations DEAE, Q, QAE could be incorporated in claims 6, 7, 10, 17 and 19.